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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 92F-0443]

Indirect Food Additives: Adhesives and Components of Coatings; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its food additives regulations to correct two typographical errors in the Chemical Abstracts Service (CAS) registry number. This document corrects those errors.

DATES: This rule is effective *[insert date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3091.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 11, 2000 (65 FR 6889), the agency amended the food additive regulations to provide for the safe use of: (1) 1,2-dibromo-2,4-dicyanobutane, and (2) a mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one, optionally containing magnesium nitrate, as antimicrobial agents in emulsion-based silicone coating formulations. The CAS registry number for 2-methyl-4-isothiazolin-3-one was incorrectly published. The agency is amending both 21 CFR 175.300 and 175.320 to correct those errors.

NFR3

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 175.300 [Amended]

2. Section 175.300 *Resinous and polymeric coatings* is amended in paragraph (b)(3)(xxxiii), under the entry “5-Chloro-2-methyl * * *”, by removing “(CAS Reg. No. 2628–20–4)” and adding in its place “(CAS Reg. No. 2682–20–4)”.

3. Section 175.320 is amended in the table in paragraph (b)(3) by revising the entry under item (iii) for “5–Chloro-2-methyl-4-isothiazolin-3-one” under the headings “List of substances” and “Limitations” to read as follows:

§ 175.320 Resinous and polymeric coatings for polyolefin films.

* * * * *

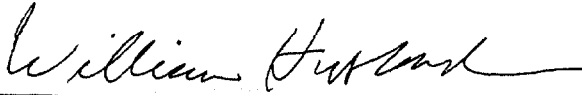
(b) * * *

(3) * * *

List of substances	Limitations
(iii) Adjuvants (release agents, waxes, and dispersants): 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172-55-4) and 2-methyl-4-isothiazolin-3-one (CAS Reg. No. 2682-20-4) mixture, at a ratio of 3 parts to 1 part, respectively, manufactured from methyl-3-mercaptopropionate (CAS Reg. No. 2935-90-2) and optionally containing magnesium nitrate (CAS Reg. No. 10377-60-3) at a concentration equivalent to the isothiazolone active ingredients (weight/weight).	For use only as an antimicrobial agent in emulsion-based silicone coatings at a level not to exceed 50 milligrams per kilogram (based on isothiazolone active ingredient) in the coating formulation.

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Dated: June 7, 2000



William K. Hubbard
Senior Associate Commissioner for Policy,
Planning, and Legislation

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